

Please cancel Claim 17.

### Remarks

#### The Present Invention

The present invention is directed to a composition comprising a fibrate dissolved in at least one structured lipid.

#### The Office Action

The Office Action made the following rejections:

- 1) Claims 1-8, 12-17 and 19-20 were rejected under 35 U.S.C. §112, second paragraph, as indefinite;
- 2) Claims 1-8, 12-17 and 19-20 were rejected under 35 U.S.C. §102(b) as being anticipated by Lacy (U.S. Patent No. 5,645,856);
- 3) Claims 1, 4-6, 15, 19 and 20 were rejected under 35 U.S.C. §102(b) as being anticipated by Sanchez (U.S. Patent No. 5,494,936); and
- 4) Claims 1-8, 12-17 and 19-20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sanchez and Lacy, individually or in combination.

#### Amendments to the Claims

The claims have been limited to fibrates and claims 2, 6-8, 13 and 17 have been cancelled.

#### Discussion of 35 U.S.C. §112, Second Paragraph Rejection

The Examiner has rejected claims 1-8, 12-17 and 19-20 under 35 U.S.C. §112, second paragraph, as being indefinite on the grounds that "The nature of the formulation in claim 1 is unclear. Claim 1 does not recite the presence of any water, yet the dependent claim recites the presence of an emulsifier."

The composition of claim 1 does not contain water. An emulsifier may be added to the composition of claim 1 to aid in dilution of the composition after oral

administration of the composition to a patient. The dependent claims incorporating emulsifiers have been cancelled. In view of the above, it is submitted that the claims are not indefinite. Withdrawal of this rejection is requested.

#### Discussion of 35 U.S.C. §102(b) Rejection Over Lacy

The Examiner has rejected claims 1-8, 12-17, 19 and 20 under 35 U.S.C. §102(b) as being anticipated by Lacy (U.S. Patent No. 5,645,856). In making this rejection, the Examiner stated that the Lacy composition "further contains Capric/caprylic triglycerides such as Miglycol and Captex (note columns 4 and 5 and Examples 6 and 7)."

Applicants acknowledge that Lacy discloses caprylic/capric triglycerides (medium chain esters). However, these materials are not structured lipids which are lipids containing saturated medium and long chain fatty acids esterified on the same glycerol molecule (see pg. 3, lines 37-38 of the present application). There is no teaching of the use of structured lipids in Lacy. Thus, Lacy does not anticipate the claims of the present application.

#### Discussion of 35 U.S.C. §102(b) Rejection Over Sanchez

The Examiner has rejected claims 1, 4-6, 15, 19 and 20 under 35 U.S.C. §102(b) as being anticipated by Sanchez (U.S. Patent No. 5,494,936).

Sanchez discloses a solution of probucol in a medium chain triglyceride. Sanchez does not disclose fenofibrate dissolved in a structured lipid. Thus Sanchez does not anticipate claims 1, 4, 5, 15, 19 and 20 as presently amended and this rejection should be withdrawn.

#### Discussion of 35 U.S.C. §103(a) Rejection

The Examiner has rejected claims 1-8, 12-17, 19 and 20 under 35 U.S.C. §103(a) as being unpatentable over Sanchez and Lacy, individually or in combination.

As pointed out above, neither Lacy nor Sanchez disclose or suggest the use of structured lipids in their formulations. They disclose the use of medium chain

triglycerides. Thus, merely selecting "a proper triglyceride" as suggested by the Examiner would not yield the presently claimed compositions, methods and capsules. The use of triglycerides in pharmaceutical compositions does not render obvious the use of structured lipids.

Withdrawal of the rejection of claims 1, 3, 4, 5, 15, 19 and 20 is respectfully requested.

#### Summary

Favorable consideration and allowance of claims 1, 3-5, 12, 14-16, 19 and 20 as presently amended is respectfully requested.

If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge Deposit Account Number 04-1644.

Respectfully submitted,

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#### **Certificate of Mailing**

I hereby certify that this Amendment is being deposited with the U.S. Postal Service with sufficient amount of postage as First Class Mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on September 19, 2001.

Susan Matz  
Susan Matz



J.S. Serial No. 09/216,242

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

In the Claims

Please amend Claim 1 to read as follows:

1. (amended) A composition comprising a [lipid-regulating agent] fibrate dissolved in at least one structured lipid.

Please amend Claim 3 to read as follows:

3. (amended) A composition of claim [2] 1 wherein the fibrate is fenofibrate.

Please amend Claim 14 to read as follows:

14. (amended) A capsule of claim [13] 12 wherein the fibrate is fenofibrate.